FACTS YOU NEED TO KNOW ABOUT LASER IN SITU KERATOMILEUSIS (LASIK) SURGERY FOR THE REDUCTION OR ELIMINATION OF MYOPIC ASTIGMATISM UP TO -12.00 D MRSE, WITH SPHERE BETWEEN >-7.00 TO -10.99 DIOPTERS OF NEARSIGHTEDNESS AND ASTIGMATISM BETWEEN 0.00 AND LESS THAN -3.00 DIOPTERS WITH THE BAUSCH AND LOMB TECHNOLAS® 217A EXCIMER LASER SYSTEM

PATIENT INFORMATION BOOKLET

Please read this entire booklet. Discuss its content with your doctor so that all your questions are answered to your satisfaction. Ask any questions you may have before you agree to the surgery.

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INTRODUCTION

This booklet contains information to help you decide whether or not to have Laser in situ Keratomileusis (LASIK) laser surgery for the correction of nearsightedness. Glasses, contact lenses, or the refractive surgical procedures known as photorefractive keratectomy (PRK) and radial keratotomy (RK) also correct nearsightedness. LASIK, using the Bausch and Lomb excimer laser system, is a completely different type of surgery than RK, but somewhat similar to PRK.

If you are nearsighted in both eyes, it may be necessary to have both eyes treated with LASIK. Sometimes, it is better to have LASIK done on only one eye. Talk with your doctor about whether it would be better to treat one eye or both eyes.

Please read this booklet completely and discuss your questions with your doctor. Only your eye care professional can determine whether or not you are a suitable candidate. Some jobs, such as military pilots, have vision requirements that RK, PRK, and LASIK presently cannot meet.

HOW THE EYE FUNCTIONS

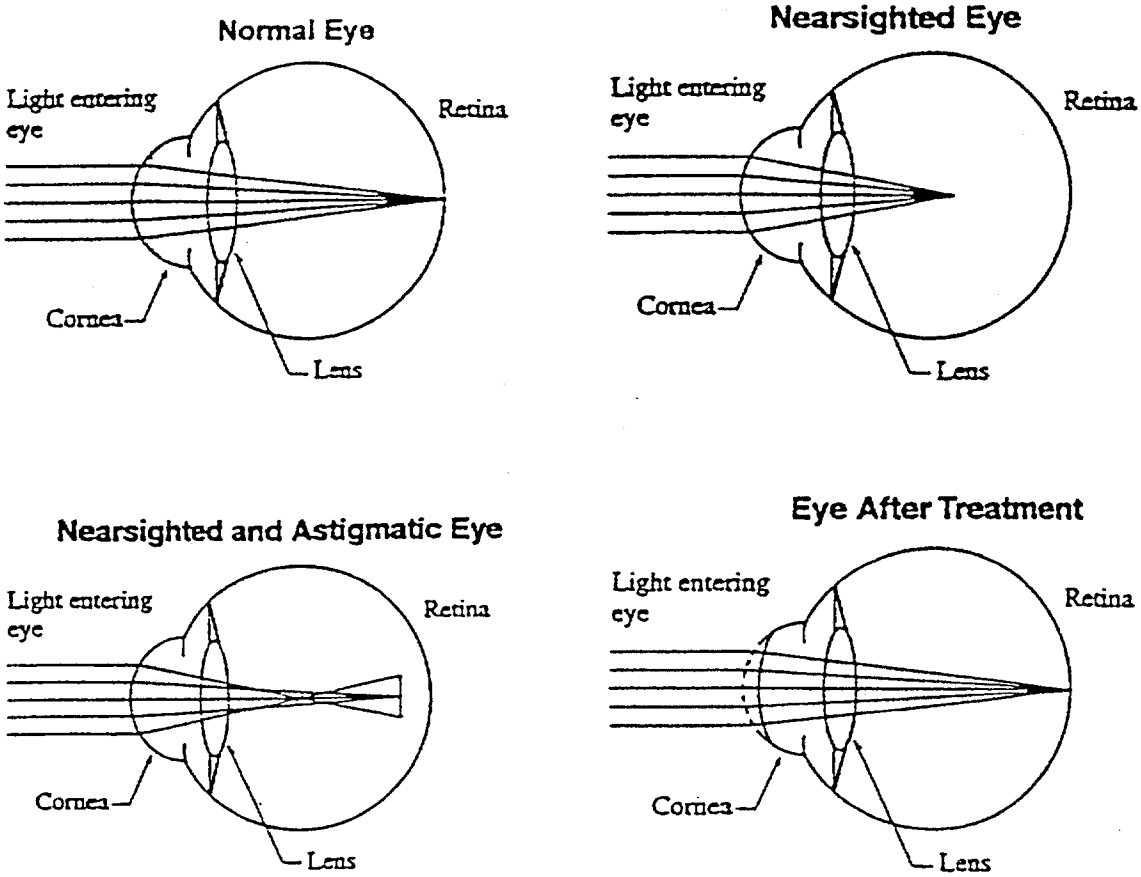
Your eye focuses light to form images or "pictures" much like a camera. Your eye changes the images into electrical signals and sends them to the brain. If your eye is out of focus, what you see is blurred.

The cornea at the front of the eye bends the light toward your retina. The clear tissue of the cornea is responsible for two-thirds of the focusing power of the eye. The lens within the eye finishes the job of focusing the light onto your retina.

Focusing with Your Eye

The eye focuses light by bending all light rays to meet at a single point. If it works perfectly, a sharp image of the object you look at will be focused exactly on the retina. You will see a clear image. However, if the light focuses either in front of or behind the retina, the image you see will be blurred. Depending on where the image focuses, you will be nearsighted, farsighted, or astigmatic.

The shape of the cornea determines the focusing power of the eye. The more sharply curved the cornea, the more that light rays are bent. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. If the cornea is curved too much, the image focuses in front of the retina and the eye is nearsighted. If the cornea is irregularly shaped (like a football rather than a basketball), it is called astigmatic.



Checking Your Focus

Your doctor checks where your eye focuses light. When your vision is corrected, a lens or a combination of lenses is added to move the point where the light focuses so that the focal point strikes your retina perfectly. Good focus depends on the shape and size of your eyeball, the shape of your cornea, and the power of your natural lens.

The Nearsighted Eye

One in four people in North America are nearsighted. They see near objects clearly, but distant objects are blurry. Light rays focus in front of the retina instead of directly on it. Nearsightedness tends to run in families. It usually starts in childhood and stabilizes in the late teens or early adulthood. Nearsightedness can be corrected by glasses, contact lenses or refractive surgery.

Glasses and contact lenses can be adjusted if vision changes over time. Changes due to refractive surgery are usually permanent and cannot be undone if vision or focus changes. If your vision changes or the initial surgery is not completely successful (which occurred in 9.7% of the cases treated in the Bausch and Lomb clinical study), additional treatments may be performed to try to

improve your results. In the Bausch and Lomb study, there were no eyes that were re-treated for myopia correction during the study period.

WHAT IS LASER IN SITU KERATOMILEUSIS (LASIK)?

LASIK is a surgical treatment for nearsightedness. A small surgical instrument called a microkeratome, which is much like a carpenter's plane, is used to make a very thin flap of tissue on the cornea (the clear part on the front of the eye). This flap is then folded out of the way, and an excimer laser is used to flatten the front surface of the cornea below the flap. The laser removes small amounts of tissue with ultraviolet light. After the laser treatment is finished, the corneal flap is placed back into its original position on the cornea. This is different from RK. In RK, a surgical knife is used to make deep cuts around the center of the cornea.

An excimer laser is a machine that produces and aims a powerful beam of ultraviolet light. The excimer laser produces a brief, intense pulse that lasts only a few billionths of a second. Each pulse removes a microscopic amount of tissue from the surface of the cornea. It produces little heat and leaves the tissue beneath unchanged.

LASIK surgery is performed on one eye at a time. The second eye can be treated if all goes well with the first eye. Laser surgery on the second eye can usually be done on the same day as the first eye, or may be done later, depending on your doctor's evaluation of your particular case.

In the clinical study of the Bausch & Lomb TECHNOLAS 217A Excimer Laser System, 53.3% of all treated eyes could see 20/20 or better without glasses after a single LASIK procedure, and 90.3% could see 20/40 or better. Although vision without glasses improved for all eyes, some patients still needed glasses or contact lenses after LASIK. LASIK to correct distance vision does not eliminate the need for reading glasses. It is possible that you may need reading glasses after laser surgery even if you did NOT wear them before.

Benefits

LASIK surgery, performed with the Bausch & Lomb TECHNOLAS 217A Excimer Laser System, is effective in reducing or eliminating nearsightedness of more than -7.00 to -10.99 diopters with astigmatism less than 3.00 diopters.

LASIK may reduce overall nearsightedness while reducing or eliminating dependency on contact lenses or glasses.

LASIK surgery, performed with the Bausch & Lomb TECHNOLAS 217A Excimer Laser System, is a reasonably safe and effective alternate way to correct nearsightedness.

Risks

To get the best possible vision, you may need to have additional LASIK surgery if your initial surgery results are not satisfactory.

In addition, it is possible that LASIK surgery may result in a decrease in your best corrected vision compared to before you had the surgery.

LASIK surgery may cause visual problems or symptoms that you did not have before the surgery, or may make such pre-existing problems or symptoms worse following the surgery.

There is a risk of infection of the cornea or other parts of the eye, as a result of the LASIK surgery, due to removal of tissue from the front surface of the eye as part of the procedure.

There is a risk of perforation (cutting completely through the cornea) of the eye during the microkeratome portion of the surgery to create the corneal flap, which could lead to loss of fluid from inside the eye, cataract formation, and infection of the eye.

During the First Week Following Surgery

- Pain and discomfort may last for up to 7 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You may be sensitive to bright lights.

For the First Week to One Month Following Surgery

- The pressure in your eye may increase due to use of anti-inflammatory medications. When you stop the medication or use other drug therapy, the pressure goes back to normal.
- Your cornea may become hazy or cloudy enough to affect your vision. This haze disappears over time. Some patients continue to experience haze up to 6 months after the surgery.

3 months After Surgery

The Bausch and Lomb clinical studies showed that for the following problems more than 1% of patients reported that these problems were worse at 3 months *after the surgery,* than before the surgery:

Patient Findings	All Treated Eyes											
	3 Months			6 Months			9 Months			≥12 Months		
	Better	No Change	Worse	Better	No Change	Worse	Better	No Change	Worse	Better	No Change	Worse
Dryness	7.9%	48.9%	43.2%	9.8%	46.2%	44.0%	13.5%	44.9%	41.5%	20.8%	37.7%	41.5%
Fluctuations of vision	8.5%	44.1%	47.4%	9.4%	48.1%	42.5%	11.1%	48.8%	40.1%	10.7%	56.0%	33.3%
Variation of vision in dim light	22.2%	43.2%	34.7%	20.3%	42.9%	36.8%	23.7%	42.5%	33.8%	24.5%	47.2%	28.3%
Blurred vision	23.7%	45.6%	30.7%	26.3%	42.5%	31.2%	27.1%	44.9%	28.0%	31.4%	44.7%	23.9%
Glare	18.2%	52.9%	28.9%	24.1%	47.0%	28.9%	20.8%	56.5%	22.7%	27.7%	55.3%	17.0%
Variation of vision in normal light	11.2%	59.9%	28.9%	12.0%	61.3%	26.7%	11.6%	62.8%	25.6%	13.2%	63.5%	23.3%
Light sensitivity	27.7%	42.6%	29.8%	28.9%	45.5%	25.6%	34.3%	44.4%	21.3%	38.4%	47.8%	13.8%
Variation of vision in bright light	19.8%	50.2%	30.1%	25.9%	50.4%	23.7%	27.5%	52.2%	20.3%	30.2%	54.7%	15.1%
Halos	11.2%	66.3%	22.5%	15.4%	63.2%	21.4%	16.4%	67.1%	16.4%	15.1%	72.3%	12.6%
Gritty feeling	10.6%	69.9%	19.5%	11.3%	67.7%	21.1%	12.6%	73.4%	14.0%	15.1%	75.5%	9.4%
Night driving vision	34.7%	46.8%	18.5%	38.7%	42.5%	18.8%	37.2%	44.0%	18.8%	41.5%	46.5%	11.9%
Ghost images	4.9%	77.5%	17.6%	6.4%	75.2%	18.4%	6.3%	81.2%	12.6%	6.3%	85.5%	8.2%
Redness	14.0%	67.5%	18.5%	13.9%	69.9%	16.2%	17.4%	68.6%	14.0%	23.9%	61.0%	15.1%
Double vision	6.1%	79.3%	14.6%	7.1%	77.8%	15.0%	6.3%	81.6%	12.1%	9.4%	79.9%	10.7%
Burning	12.8%	72.9%	14.3%	14.3%	71.4%	14.3%	15.5%	71.0%	13.5%	17.6%	73.0%	9.4%
Pain	7.9%	83.9%	8.2%	9.0%	85.3%	5.6%	10.1%	85.5%	4.3%	9.4%	89.3%	1.3%
Tearing	17.0%	79.9%	3.0%	18.0%	76.3%	5.6%	17.9%	76.8%	5.3%	24.5%	70.4%	5.0%
Headaches	23.4%	69.0%	7.6%	28.9%	66.2%	4.9%	27.5%	69.6%	2.9%	32.1%	61.6%	6.3%
Eye strain	1.2%	98.8%	0.0%	1.5%	97.4%	1.1%	1.9%	97.6%	0.5%	0.0%	100.0%	0.0%
Allergies	1.2%	98.2%	0.6%	0.4%	99.6%	0.0%	0.5%	99.0%	0.5%	0.6%	98.1%	1.3%

N = Number of Self-evaluation Forms received with non-missing values at each visit.

During the clinical trial of LASIK, less than 1% of **patients** reported the following effects of their LASIK surgery at 6 months after the surgery:

Astigmatism and light flashes.

During the Bausch and Lomb clinical trials, **doctors** reported the following complications:

Early complications (during the first few weeks after LASIK)

Allergies, anterior membrane dystrophy, blepharitis, blurry vision, conjunctival injection, conjunctivitis, corneal abrasion, corneal edema, corneal edema (flap), debris in interface, double vision, edema, epithelial defect, epithelial ingrowth, epithelium in the interface, epithelium in the interface with loss ≤ 2 lines of BSCVA, erosion, folds in flap, ghost images, guttata, heart attack, lamellar keratitis, papillae, partial flap, peripheral corneal epithelial defect (on the flap), procedure aborted, secondary surgical intervention other than excimer laser treatment, subconjunctival hemorrhage, and vitreal traction.

Medium-term complications (3 months after surgery)

Anterior membrane dystrophy, blepharitis, conjunctivitis, debris in interface, epithelial defect, epithelial ingrowth, epithelium in the interface with loss ≤ 2 lines of BSCVA, folds in flap, interface disruption, papillae, and posterior vitreous detachment.

Long-term complications (6 months after surgery)

Angioplasty, anterior membrane dystrophy, bells palsy, blepharitis, bowmans wrinkle, chalazion, conjunctivitis, corneal edema (flap), debris in interface, decrease in BSCVA of > 2 lines not due to irregular astigmatism, double vision, edema, epiretinal membrane, epithelial ingrowth, epithelium in the interface with loss ≤ 2 lines of BSCVA, folds in flap, guttata, itching, keratitis, meibomitis, mini-stroke, opacity, crystalline lens, pain, peripheral corneal epithelial defect (on the flap), pterygium, punctal stenosis, redness, sebaceous cyst, subepithelial opacity, trichiasis, vitreous detachment.

Indications for use

The Bausch & Lomb TECHNOLAS 217A Excimer Laser System is indicated for laser in-situ keratomileusis (LASIK) treatments:

- for the reduction or elimination of myopic astigmatism up to -12.00 D MRSE, with sphere between >-7.00 D to -10.99 D and cylinder between 0.00 and <-3.00 D;
- in patients with documented evidence of a change in manifest refraction of less than or equal to 0.50 diopters (in both cylinder and sphere components) for at least one year prior to the date of the pre-operative examination; and,
- in patients who are 21 years of age or older.

Contraindications

You should **NOT** have LASIK surgery if:

- You have collagen, vascular, autoimmune, or immunodeficiency disease (e.g., lupus or AIDS).
- You are pregnant or nursing.
- You show signs of keratoconus (a corneal disease) or have any other condition that causes thinning of your cornea.
- You are taking Accutane (isotretinoin) for acne treatment or Cordarone (amiodarone hydrochloride) for controlling normal heart rhythm.

Warnings

Discuss with your doctor if:

- You have a systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease or an immunocompromised status.
- You have had *Herpes simplex* or *Herpes* zoster infections.

Precautions

The safety and effectiveness of the Bausch & Lomb TECHNOLAS 217A Excimer Laser System have **NOT** been established:

- In patients with unstable or worsening nearsightedness or astigmatism.
- In patients with diseased or abnormal corneas (scars, infections, etc.).
- In patients with previous surgery or injury to the center of the cornea where LASIK will be performed.
- In patients with abnormal blood vessels within 1.0 mm of the center of the eye where LASIK will be performed.
- In patients under 21 years of age.
- In patients taking hormone replacement therapy or antihistamines.
- In patients taking sumatripin (Imitrex) for migraine headaches.
- In patients with a history of glaucoma.
- In patients with refractive treatments >11 D of nearsightedness and ≥ 3.0D of astigmatism.
- In patients with corneas too thin for the procedure to be completed.
- In patients with a tendency to form scars.
- Over the longer term (more than 6 months after surgery).

The effects of LASIK on visual performance under poor lighting conditions have not been determined. It is possible, following LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes.

For treatment of myopic astigmatism equal to or greater than –12.00D MRSE.
Patients 50 years of age and older may be likely to experience a reduction in predictability of outcomes (as compared to younger patients).

ARE YOU A GOOD CANDIDATE FOR LASIK?

If you are considering LASIK, you must:

- Be 21 years of age or older.
- Have healthy eyes free from retinal problems, corneal scars, and any eye disease.
- Have total myopic astigmatism of -12.00 D (spherical equivalent refraction) or less.
- Have nearsightedness within the range of treatment: >-7.00 to -10.99 diopters with less than -3.00 diopters of astigmatism.
- Have written proof that the change in your vision is one-half diopter or less per year for at least one year before your pre-surgery exam.

- Be fully informed about the risks and benefits of LASIK as compared to other treatments for nearsightedness.
- Be able to lie flat without difficulty.
- Be able to keep your eye accurately on the red fixation light during the entire LASIK procedure.
- Be willing to sign an Informed Consent Form provided by your eye care professional.
- Be able to tolerate eye drops to numb your eye.

WHAT YOU NEED TO KNOW ABOUT THE SURGERY

Before the Surgery

If you are interested in LASIK, you will need a pre-surgical examination to determine if your eye is healthy and suitable for LASIK. The exam includes a physical and eye history. Both eyes will be checked. Your cornea will be mapped by computer to determine if it is smooth and properly shaped.

WARNING: If you wear contact lenses, the doctor will ask you to stop wearing them two to four weeks before your exam. Failure to do this may produce poor surgical results.

Before surgery, talk to your doctor about any medicine you take. Also discuss whether or not you should eat and drink just before surgery. You should arrange to have someone drive you home after surgery and to your next doctor's appointment. You should not drive until your doctor gives you permission.

The Day of Surgery

Before the actual surgery, you will be given the opportunity to hear the sounds the laser makes so that you will be prepared for the noise during surgery. You will be given some numbing drops in the eye that will be treated. When you go into the room that contains the laser system, you will see a large machine that has a computer screen, a surgeon's chair and a patient bed. You will be asked to lie down on the bed. You will lay face up toward the laser's microscope and the ceiling. Your eye may be numbed with more drops. The eye not having surgery may be covered with a temporary shield.

The surgery takes about 10-20 minutes overall. The use of the laser, however, lasts only about 30 to 60 seconds. The doctor will place a small spring-like device between your eyelids to hold them open.

When the surgery begins, the surgeon will use a small instrument to create a thin flap of corneal tissue that is folded away from the cornea. The doctor will then reposition your head under the microscope. You will be asked to look directly at the red light. Even though the eye not having

the surgery may be covered by a drape or a patch, try to keep both eyes open without squinting. This makes it easier to keep looking at the red light. You will then hear the noise the laser makes when it is delivering the laser energy.

WARNING: It is very important that you keep looking directly at the red light, even if the light fades or dims. Your results depend on how well you look directly at this red light throughout the treatment.

Immediately After the Surgery

After the surgery, your doctor will put some medicated drops or ointment into your eye. Your doctor may apply a patch or protective shield to your eye for protection and comfort.

Numbing drops make the surgery painless. When these drops wear off, your eye may hurt for a day or two. Most patients describe the pain as moderate to severe. Your doctor may prescribe pain medicine to make you more comfortable. Do not remove the patch or shield until instructed to do so. Do not rub or touch your treated eye for the first one to seven days after surgery.

First Days After Surgery

The patch or shield is usually removed the next day. You may be mildly sensitive to light and glare. Wearing sunglasses may make you more comfortable. You may also have the feeling that something is in your eye. This happens while the outer layer of your cornea is healing.

Your vision should stabilize within a few weeks. Some patients report small changes in vision such as improvement or worsening. These changes may occur up to six months or more after surgery.

You may see a haze or cloudiness in the cornea following surgery. It usually does not affect your vision. This haze tends to decrease over time. It usually disappears completely by 12 to 24 months after the surgery.

Use any prescribed drops and lubricants as directed by your doctor. Your surgical results depend on carefully following your doctor's directions.

QUESTIONS TO ASK YOUR DOCTOR

- What are the other options for correcting nearsightedness?
- Will I have to limit my activities after the treatment? If yes, for how long?
- What are the benefits of LASIK for my level of nearsightedness?
- What vision can I expect in the first few months after surgery?

- If LASIK does not correct my vision, could my vision be worse than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses if I still need them after LASIK?
- How is LASIK likely to affect my need to use glasses or contact lenses as I get older?
- Will my cornea heal differently if I injure it after having LASIK?
- Should I have LASIK surgery in my other eye?
- How long will I have to wait before I can have LASIK surgery on my other eye?
- What vision problems will I experience if I have LASIK only in one eye?

Discuss the cost of surgery and follow-up care with your doctor. Most health insurance policies do not cover excimer laser treatment for vision correction.

SUMMARY OF IMPORTANT INFORMATION

- LASIK is permanent. Once performed, it is not reversible.
- LASIK does **NOT** eliminate the need for reading glasses, even if you have never worn them.
- Your vision must be stable for at least one year before LASIK surgery. You will need written proof that your nearsightedness has not changed by more than 0.50 diopters.
- Pregnant and nursing women should wait to have the surgery.
- You would not be a good candidate if you have any medical condition that makes wound healing difficult.
- The LASIK treatment may cause you discomfort.
- The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks, before you agree to the treatment.
- LASIK is not a laser version of radial keratotomy (RK). These operations are completely different from each other.
- Some alternatives to LASIK include glasses, contact lenses, photorefractive keratectomy (PRK), and RK.
- Some jobs, such as military pilots, have vision requirements that RK, PRK, or LASIK do not presently meet.

Before considering LASIK you should:

Have a complete eye examination.

Talk with one or more eye care professionals about the potential benefits of LASIK and the complications, risks and time required for healing.

GLOSSARY OF TERMS

astigmatism: Refractive error which prevents light rays from coming to a single point of focus on the retina because of different degrees of bending of light by the various meridians of the eye.

cornea: Transparent front portion of the eye that covers the iris, pupil, and anterior chamber, and provides most of an eye's optical focusing power.

diopter: Unit of measurement of optical strength or refractive power of lenses.

excimer laser: A medical device that produces a very powerful and pure beam of light of a single specific wavelength (color) that is used to remove tissue from the clear front part of the eye (cornea). This is done in a computer-controlled fashion to re-shape the cornea to correct refractive errors. This re-shaping allows incoming light rays to be more accurately focused on the retina.

farsightedness/ hyperopia: Condition in which the eye is "under-powered," so that parallel light rays from a distant object strike the retina before coming to a sharp focus; true focal point is said to be "behind the retina." Corrected with additional optical power, supplied by a "plus" lens or by additional use of the eye's own focusing ability.

halos: Hazy ring around bright lights seen by some patients with refractive error or optical defects (e.g., cataracts or corneal swelling).

keratoconus: Hereditary, degenerative corneal disease characterized by generalized thinning and cone-shaped protrusion of the central cornea.

LASIK: An acronym for "laser in situ keratomileusis." This is a surgical procedure in which a very thin flap of tissue on the clear front part of the eye (cornea) is made using a small surgical instrument called a microkeratome, which is much like a carpenter's plane. The flap is then folded out of the way and an excimer laser is used to flatten the front surface of the cornea below the flap.

lens: A transparent, colorless body located in the front third of the eyeball, between the aqueous and the vitreous, the function of which is to help bring rays of light to focus on the retina.

nearsightedness/ myopia: "Overpowered" eye in which parallel light rays from a distant object are brought to focus in front of the retina. Requires "minus" lens correction to "weaken" the eye optically and permit clear distance vision.

pupil: The opening at the center of the iris of the eye for the transmission of light, which varies in diameter depending upon the brightness of the light coming into the eye.

PRK: An acronym for "photorefractive keratectomy." This is a surgical procedure in which a thin portion of the clear front part of the eye (cornea) is removed by the excimer laser in a predetermined manner to re-shape the cornea to correct refractive errors of the eye.

refractive surgery: Several different procedures used for altering the shape of the cornea and thus how it bends light, in order to change or correct the eye's refractive error.

retina: The thin lining of the back of the eye that converts images from the eye's optical system into electrical impulses sent to the brain.

RK An acronym for "radial keratotomy." This is a surgical procedure in which a predetermined number of radial cuts are made in the periphery of the cornea. This allows the central cornea to flatten and thereby reduces nearsightedness.

PATIENT ASSISTANCE INFORMATION

PRIMARY EYE CARE PROFESSIONAL

Name:
Address:

Telephone Number:

LASIK DOCTOR

Name:
Address:

Telephone Number:

LOCATION WHERE TREATMENT WAS DONE

Name:
Address:

Telephone Number:

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